Instructions for Preparation and Submission of a Letter of Intent for Merit Review, MREP and Deployment Health Research applications for Fall 2004 Submission

BLR&D and CSR&D Services

Standard Letter of Intent(LOI)
LOI for the Clinical Research Program (CLIN)
LOI for the Epidemiology Research Program (EPID)
LOI for Deployment Health Research
LOI for the Merit Review Entry Program (MREP)
LOI Submission

All Merit Review programs, including Clinical Research Program (CLIN) and Epidemiology Research Program (EPID) require a letter of intent (LOI) prior to submitting applications. In addition, applications to the Merit Review Entry Program (MREP) and Deployment Health Research Initiative also require an LOI. LOIs will NOT be evaluated for scientific merit, but rather to assess assignments to the appropriate Service (BLR&D or CSR&D) and to the appropriate Merit Review Subcommittees. The LOIs for special programs (CLIN, EPID, Deployment Health Research and MREP) will also be evaluated for program-specific requirements.

If you are unsure of whether your study meets the requirements for a special Merit Review program or the Deployment Health Research Initiative, be sure to discuss submission requirements with the ACOS for R&D or contact the appropriate Program Manager in BLR&D/CSR&D at VA Central Office.

Standard Letter of Intent

A standard Merit Review LOI consists of the following:

a) VHA Research & Development Letter Of Intent Cover Page (VA Form 10-1313-13)

VA Form 10-1313-13 has been revised (Revised May 2004) for the Fall 2004 review cycle. DO NOT USE PREVIOUS VERSIONS.

Instructions for VA Form 10-1313-13 (Boxes 1-5):

Box 1. Select the appropriate service (BLR&D or CSR&D) based on the nature of your proposed study. Use the following guidelines for BLR&D and CSR&D purviews:
The BLR&D purview includes laboratory studies, both *in vitro* and *in vivo*, including tissue culture and animal models; and studies on human biological samples. The CSR&D purview includes studies on whole human subjects involving interventional or exploratory procedures (with the exception of procedures for obtaining biological samples such as drawing blood, buccal swabs etc.)
Next, select a portfolio from the drop-down list for BLR&D or CSR&D service. For a description of the portfolios, refer to the purview of BLR&D/CSR&D Merit Review Subcommittees. This selection is a recommendation only. Program Review will make all final assignments.

Box 2. Select "New", if the LOI is for the first submission of the proposed research or the first LOI submission for a competitive renewal of an ongoing project. *Note: This definition of "new" is valid only for an LOI submission and may differ for a full proposal submission*. If this is not a new LOI, you should select either "Revision" or "Resubmission." Select "Revision," if the there are any substantive changes in the scientific component of the study (e.g., number and scope of specific aims or methodology proposed) since the previous LOI submission. Select "Resubmission," if there are no substantive changes in the scientific component of the study since the previous LOI submission.

Box 3. Select the appropriate program and level. For Merit Review, indicate whether it is a Standard Merit Review or one of the special Merit Review programs. If you select Clinical Research Program in Box 3, your portfolio selection in Box 1 should be CLIN, and if you select Epidemiology Research Program in Box 3, your portfolio selection in Box 1 should be EPID. If you are applying to the MREP, select MREP under Training Programs in Box 3 AND select a portfolio in Box 1. If you are responding to Deployment Health Research RFA, select response to specific announcement under "Other Programs" in Box 3, type in "Deployment Health Research" for the RFA title AND select a portfolio in Box 1.

Box 4. Limit the title to a total of 72 characters, including spaces.

Box 5. A proposal may have only one principal investigator. As per current policy, BLR&D and CSR&D Services do not allow co-PIs (see Handbook 1202.1).

b) Study Description (2-page limit; 1 inch margins and no smaller than 12-point font). Succinctly addresses each of the following:

1) Hypothesis(es)/Research Questions
2) Discrete Study Objectives
3) Description of Relevance to VA
4) Overview of Design/Methods
   Note: This section should include a clear statement of the model(s) of choice for the study, i.e., human, animal, cell culture etc.
5) Description of Intervention(s)/Treatment(s) - *if applicable*
6) Total Budget
   Note: In rare instances, permission may be granted to exceed the budget caps. If you are requesting permission to exceed the budget cap(s) (annual budget and/or equipment) clearly state the request and provide justification.

c) Statement of Disclosure - 1-2 sentence statement from the PI indicating that no financial or contractual relationship exists between any organization involved in the proposed study that could constitute a real or apparent conflict of interest (including all investigators and collaborators who plan to devote 5 percent or more effort to the proposed project). If such a relationship or contract does exist, full disclosure must be provided.

d) Acknowledgment of the VA policy to include women and minorities in research (if applicable).

e) References: Up to five reference citations relevant to the proposed study.

LOI for the Clinical Research Program (CLIN)

If you are submitting an LOI for the Clinical Research program (CLIN), use the standard LOI format, but be sure to address the following under the study description:

a) **Overview of Design/Methods**- clarify the following aspects of the study:
- Phase of the clinical trial (I, II, III or IV) (*Note: LOIs for Phase I studies must have prior approval from the CRADO*)
- Open label, randomized, blinded, or double blinded
- Single site or multi-site *(Note: If the study involves more than one site, provide justification)*
- Study population(s) and sample size
- Study endpoints

b) **Description of Intervention(s)/Treatment(s)**

c) **Total Budget and Study Duration**
Note: In rare instances, permission may be granted to exceed the budget cap and study duration limit. If you are requesting permission to exceed the budget cap(s) (annual budget and/or equipment budget) and/or the study duration limit of 3 years, include a clear statement of the request(s) and provide justification.

LOI for the Epidemiology Research Program (EPID)

If you are submitting an LOI for the Epidemiology Research Program (EPID), use the Standard LOI format, but be sure to address the following in the study description:

a) **Overview of Design/Methods should include**
- Description of study population(s), if applicable
- Subject recruitment procedures, if applicable
- Description of sampling methods
- Description of experimental measures to be evaluated, methods of procedure and links between data and proposed measures
- Data analysis plan

LOI for Deployment Health Research

If you are submitting an LOI for the Deployment Health Research Initiative, use the standard LOI format, but be sure to address the following in the study description:

a) **Hypothesis and Research Questions:**
- Describe clearly how the proposed study is deployment-related
- If the study involves a deployed population, specify the deployment (Gulf War I, Operation Enduring Freedom, etc.)

b) **Total Budget and Study Duration:**
Note: In rare instances, permission may be granted to exceed the budget cap and study duration limit. If you are requesting permission to exceed the budget cap(s) (annual budget and/or equipment budget) and/or the study duration limit of 3 years, include a clear statement of the request(s) and provide justification.

LOI for the Merit Review Entry Program (MREP)

If you are submitting an LOI for an MREP application, you are required to submit the standard LOI plus the following:

a) Supplemental page for MREP LOI (two- page limit)
b) VA Combined Biographical Form 10-1313-5/6 for applicant
c) VA Combined Biographical Form 10-1313-5/6 for each mentor (limit 3)

LOI Submission

The deadline for LOI submission to BLR&D/CSR&D for the Fall 2004 Review is July 15, 2004. Early submission of LOIs is encouraged.

Submit the original and 3 copies, reproduced back-to-back, to the following address via courier:

Department of Veterans Affairs
BLR&D/CSR&D Letter Of Intent
Program Management Division (121E)
810 Vermont Avenue NW
Washington DC 20420

Telephone Number for Courier Delivery: 202-254-0183/84